1103326-0678

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

RECEIVED

Applicant

A. Bayati

OCT 1 5 200%

Serial No.

10/053,279

Examiner: Michael Hartley

Filed

January 17, 2002

Group Art Unit: 1616

For

THERAPY FOR FUNCTIONAL DYSPEPSIA

I hereby certify that this paper is being facsimile transmitted to The U.S. Patent and Trademark Office, Alexandria, VA 22313-1450, on October 15, 2004.

Richard JA Stern

35,372

PTO Reg. No.

Signature Signature

October 15, 2004

Date of Signature

Attn: Examiner M. Hartley

Art Unit: 1616

Facsimile No.: 703-872-9306

No. of pages: 22

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

In compliance with 37 CFR \$1.56 and in accordance with 37 CFR \$\$1.97 and 1.98, it is requested that the two (2) references listed on the attached Form PTO/SB/08A be made of record in this application. Copies of the references are enclosed.

BEST AVAILABLE COPY

In accordance with 35 CFR §\$1.97(g) and (h), the filing of this Information Disclosure Statement shall not be construed as a representation that a search has been made or that the information is material to patentability as defined in 37 CFR \$1.56(b).

The two references cited herein are the Master of Science
Thesis of Maria Nordling and an abstract thereof. The abstract
was printed and copies were distributed to appropriate faculty
members at the University of Uppsala. The thesis itself was
presented orally to approximately ten people. The thesis was
not distributed, nor was it housed or cataloged in the
University library.

These documents are submitted under 37 CFR §1.97(c), i.e., after the mailing of a first Office Action but prior to the mailing of a final Office Action. The Commissioner is hereby authorized to charge the fee set forth in 37 CFR §1.17(p) to Deposit Account No. 23-1703. Any other fees which may be due for any reason in connection with this communication may likewise be charged.

Dated: October 15, 2004

Respectfully submitted,

Richard J. Sterner Reg. No. 35,372 Agent for Applicant

Customer No. 007470 White & Case LLP

Direct Dial: (212) 819-8783

Enclosures

PTO/SB/08A (08-03)

Pages, Columns, Lines, Where

Approved for use through 07/31/2006. OMB 0651-0031 U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE Index the Paperwork Reduction Act of 1993, no persons are required to respond to a coffection of information unless is contains a valid OWB committee of the paper of information unless is contains a valid OWB committee of the paper of the pape

Name of Patentee

		Ottoer me Pt	Serwork Reduction Act of 1995, no per-	ions are required to respond to a collection of	Autouvation furiess it committee a ANTA C	MH control member.	
Substitute for form 1449/PTO				Complete if Known			
17403414	ic to: 101111 1445/1 10			Application Number	10/053,279		
	INFORMATIO	NI DIC	CLOSUDE	Filing Date	January 17, 2002		
				First Named Inventor	A. Bayati		
	STATEMENT	BY AF	PLICANT	Art Unit	1616	;	
	(Use as many	sheets as nec	essary)	Examiner Name	Michael Hartley		
Sheet	1	of	1	Attorney Docket Number	1103326-0678		

U.S. PATENT DOCUMENTS

Publication Date

Initials*	No.1	Number-Kind Code ² ((brown)	MM-DD-YYYY	Applicant of Cited Document	Relevant Passages/Figures Appea						
		· · · · · · · · · · · · · · · · · · ·				 _					
	-		·····		<u> </u>						
			:								
				<u> </u>	, 	····					
			· · · · · · · · · · · · · · · · · · ·			 .					
			N PATENT DO								
Examiner Initials	Cite No.1	Foreign Patent Document	Publication Date MM-DD-YYYY		Pages, Columns, Lines, W Relevant Passages Or Rel	mmer !-					
		Country Code3-Number4-Kind Code5(if known)		Document	Figures Appear.	cvant 1					
	<u> </u>		<u> </u>								
	 -										
		<u> </u>	<u> </u>		·						
		NON DATENT	r r isted Astini	P-DOCHMENTS							
Examiner	Cite	NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, include name of the author (in CAPITAL LETTERS)).									
Initials*	No.	scrial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.									
	1	M. NORDLING, "A Comparative Study of Gastric Distension in Different Rat Strains," Master of Science Thesis, University of Uppsala, Sweden, 2000									
	2	M. NORDLING, Abstract of Cite	No. 1.			1::					
*****					······································	100					
	<u> </u>	. ;				4.					
	1			•							
											
				•		\ "					
	+			· · · · · · · · · · · · · · · · · · ·							
				•		1					
	 					_					
						7.7					
	1	1				[

EXAMPLER: Initial if references considered, whether or not citation is in confirmance with MPEP MP. Draw-line through children in combination shall not considered, include copy of this farm with acest consistences to applicate. Application is trained color of MPEP MP. Draw-line through children is combinated and include copy of this farm with acest consistences are greatly consistenced. The first are greatly appropriate symbols as induced to the document. By the revolution of the person of the first are greatly appropriate symbols as induced on the document under WIPO Standard ST.). For particular to place a check must be not if inglish barpage Transistion is standard. This ordination is required by TR. 1.7 and 1.78. The information is required to obtain or retain a branch by the public which is to like (and by the UFFTO is proposed) appropriate. Confidentially is governed by 37 U.S.C. 122 and 37 CFR. 1.14. This collection is take 2 hours to complete, including gathering, preparing and submitting the completed updication form to the USFTO. These will vary deposing upon the individual cases. Any comments on the annotate of these completed in those annotated the secure to the Child Information Officer, U.S. Patent and Tradestarts Office, P.O. But 1450, Abrunders. VA 22313-1450. DO NOT SINKO FEES OR CONFILETED FORM TO THIS ADDRESS. SAND TO: Commissioner for Present, P.O. But 1450, Abrunders.

Date Considered

Examiner Signature

Cite

Examiner

Document Number

Abstract

Functional dyspepsia (FD) is characterized by nausea, vomiting, bloating, feelings of fullness early satiety and epigastric pain, but the pathology is unknown. In many of the FD-patients, the proximal stomach is unable to relax in response to food. In others, the gastric motility or gastric emptying is impaired. Almost all of the FD patients report that they have been exposed to one or more social stressors for more than a year. It has been shown that stress alters the motility, and it may have altered the gastric motility in FD patients, leading to dyspeptic symptoms.

In order to investigate if stress also affects gastric accommodation in animals, the gastric volume response to balloon distension was compared in Sprague Dawley (SPRD) male and female rats and Wistar Kyoto (WKY) male rats, the latter being a rat very sensitive to stress.

A barostat system was coupled to a balloon, which was inserted into the stomach of the rat via a fistula. The barostat system was then connected to a program which produced the desired pressure: 10 min ramp distension up to 10 mmHg followed by 10 min tonic distension at 10 mmHg and then a decrease to 1 mmHg (the same as the starting pressure). The pressure and volume from the experiments were entered in a data program, and different parameters were then calculated from these data.

There were no significant differences between the groups in the basal tone or elasticity in the stomach muscle. Neither were there any significant differences between the groups regarding the threshold values when the adaptive reflex-mediated relaxation had started. It was also shown that there were no significant differences in any of the parameters between the SPRD female and male rats. However the adaptive relaxation was significantly impaired in WKY rats compared with both the SPRD male and female rats.

It was shown that the properties of the stomach muscle basal tone and tension were not impaired in WKY rats. The adaptive relaxation in response to distension was, on the other hand impaired, which indicates a defect in the reflex pathway in WKY rats.

The results show that the WKY rat, which is considered to be very sensitive to stress, has impaired gastric relaxation in response to gastric distension. This is in agreement with the pattern seen in some dyspeptic patients who have impaired adaptive relaxation related to a meal.

This Page is Inserted by IFW Indexing and Scanning Operations and is not part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:
□ BLACK BORDERS
☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
☐ FADED TEXT OR DRAWING
☐ BLURRED OR ILLEGIBLE TEXT OR DRAWING
☐ SKEWED/SLANTED IMAGES
COLOR OR BLACK AND WHITE PHOTOGRAPHS
GRAY SCALE DOCUMENTS
☐ LINES OR MARKS ON ORIGINAL DOCUMENT
☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY

IMAGES ARE BEST AVAILABLE COPY.

OTHER:

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.